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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/753,355	12/29/2000	William F. Polley	56301P551	9724
8791	7590	10/15/2003	EXAMINER FLYNN, AMANDA R	
BLAKELY SOKOLOFF TAYLOR & ZAFMAN 12400 WILSHIRE BOULEVARD, SEVENTH FLOOR LOS ANGELES, CA 90025			ART UNIT 3743	
			PAPER NUMBER	

DATE MAILED: 10/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/753,355

Applicant(s)

POLLEY ET AL

Examiner

Amanda R. Flynn

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 16-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 16.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114 was filed in this application after a Notice of Appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 14 August 2003 has been entered.

### ***Claim Objections***

2. Claim 30 is objected to because of the following informalities: It is unclear if one only finger tab portion is required to have the stated shape, or if both finger tab portions claimed in the preceding claim must have the stated shape. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 16 and 18-24 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Number 5,489,273 to Whitney et al.

Whitney et al. disclose an introducer (10) for an intravascular device comprising two finger tab portions (18, 20), a tube portion (12) and a hinge portion (the substantially vertical extensions of 18, 20 in Figure 3) between the finger tab portion and the tube portion. During use

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of the introducer, the user exerts pressure in the direction of Z and Z' (Figure 3) to close the finger tab portions about the hinge portion, and to split the tube along a scoreline (40, 42).

Inasmuch as the term "seamless" has been defined, the finger tab portions, the tube portion and the hinge portion form a seamless introducer. Further, Whitney et al. state that the tube portion and finger tab/hinge portions are integrally formed into one piece through molding (see column 5, lines 13-20). As seen in the figures, the tube is substantially hollow and the finger tab portions are substantially rectangular.

5. Claims 25, 28 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent number 4,983,168 to Moorehead.

Moorehead discloses a one-piece introducer comprising a substantially hollow tube (20), with first and second finger tabs (46, 48) formed at a proximal end of the tube as a single integral piece with the tube. Inasmuch as the term "scoreline" has been defined, Moorehead discloses a scoreline (29) formed along the tube. As seen in Figure 1, the scoreline extends to the beveled distal tip (24) of the introducer.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Whitney et al. in view of U.S. Patent Number 5,263,938 to Orr et al.

Whitney et al. disclose the previously described introducer, but do not specify that the introducer can be made of polycarbonate.

Orr et al. disclose an introducer assembly that is made of polycarbonate, for its “semi-rigid” properties (col. 3, lines 34-37).

It would have been obvious to one skilled in the art at the time the invention was made to have provided the introducer as disclosed by Whitney et al., with a polycarbonate material as taught by Orr et al., to improve the semi-rigid properties of the device.

8. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moorehead in view of U.S. Patent Number 5,782,817 to Franzel et al.

Moorehead discloses the previously described one-piece introducer, but does not specify that a safety valve be coupled to the proximal end of the introducer.

Franzel et al. disclose an introducer with a toroidal safety valve (18) on the proximal end of the introducer, to prevent backflow of blood (col. 2, lines 58-60).

It would have been obvious to one skilled in the art at the time the invention was made to have provided the introducer as disclosed by Moorehead, with a safety valve as taught by Franzel et al., to prevent backflow of blood during use.

9. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moorehead in view of U.S. Patent Number 5,263,938 to Orr et al.

Moorehead discloses the previously described one-piece introducer, but does not specify that the introducer can be made of polycarbonate.

Orr et al. disclose an introducer assembly that is made of polycarbonate, for its “semi-rigid” properties (col. 3, lines 34-37).

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It would have been obvious to one skilled in the art at the time the invention was made to have provided the introducer as disclosed by Moorehead, with a polycarbonate material as taught by Orr et al., to improve the semi-rigid properties of the device.

10. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moorehead in view of U.S. Patent Number 5,334,157 to Klein et al.

Moorehead discloses the previously described one-piece introducer comprising first and second finger tabs. Moorehead does not specify the shape of the finger tabs.

Klein et al. disclose an introducer having two finger tab portions. Klein et al. show that the finger tab portions have a rectangular shape, to provide easily graspable finger tabs.

It would have been obvious to one skilled in the art at the time the invention was made to have provided the one-piece introducer as disclosed by Moorehead with rectangular finger tabs, as taught by Klein et al., to provide easily graspable finger tabs.

### ***Conclusion***

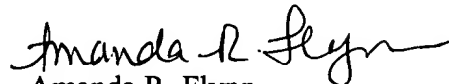
11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited art discloses introducers having features in common with the instant invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda R. Flynn whose telephone number is 703-306-4056. The examiner can normally be reached on Monday-Thursday, 8:30 - 6:00 and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1113.



Amanda R. Flynn  
Examiner  
Art Unit 3743

arf  
arf



Henry Bennett  
Supervisory Patent Examiner  
Group 3700